In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1479V UNPUBLISHED

TONY RIDDELL,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 4, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On September 25, 2019, Tony Riddell filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleged that he suffered a right shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving the influenza ("flu") vaccine on November 2, 2017. Petition at 1, ¶ 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find there is preponderant evidence establishing that the onset of Petitioner's SIRVA occurred within 48 hours of vaccination.

I. Relevant Procedural History

Along with the Petition, Mr. Riddell filed his affidavit and the medical records required by the Vaccine Act. Exhibits 1-9, ECF No. 1; see Section 11(c). During the initial status conference, held on December 30, 2019, Respondent's counsel questioned whether there were outstanding medical records, including any additional physical therapy ("PT") records from prior to or after vaccination, or whether a workers' compensation claim had been filed. See Scheduling Order at 1, ECF No. 10.

On May 4, 2020, Petitioner filed a status report indicating that he did not have a primary care provider ("PCP") prior to vaccination; that he did not undergo any additional PT, prior to or post-vaccination, for which the records have not been filed; that he is unable to provide claims summaries from his insurance company which has gone out of business; and that he did not file a workers' compensation claim. ECF No. 13. To support his statement regarding the lack of a workers' compensation claim, Petitioner filed a statement from the Kentucky Labor Cabinet, Department of Workers' Compensation, indicating there was no documentation regarding a claim for Petitioner's 2017 injury. Exhibit 10, filed May 7, 2020, ECF No. 15.

On December 17, 2020, Respondent filed a status report indicating he "[wa]s interested in pursuing settlement negotiations." ECF No. 22. Approximately four months later, however, the parties filed a joint status report indicating they "ha[d] reached an impasse in [their] settlement discussions" and Respondent wished to file his Rule 4(c) Report, setting forth his objections to compensation. ECF No. 25.

In his Rule 4(c) Report, filed on June 8, 2021, Respondent argued that Petitioner's injury did not meet the definition for a Table SIRVA³ because Petitioner had failed to

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the

³ Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV) (2017). The criteria establishing a SIRVA under the accompanying Qualification and Aids to Interpretation ("QAI") are as follows:

establish that his pain began within 48 hours of vaccination, and was limited to the shoulder in which he received the flu vaccine. Rule 4(c) Report at 6-7, ECF No. 26. Also, regarding a potential causation in fact claim, Respondent asserted Petitioner could not satisfy the three-pronged test for causation.⁴ Rule 4(c) Report at 7-8. Specifically, he argued that the statement from Petitioner's orthopedist (indicating that Petitioner suffered an inflammatory response to the flu vaccine) was not sufficient to satisfy his burden of proof for causation. *Id.*

During a call, held on July 8, 2021, the parties agreed that a fact ruling regarding the onset of Petitioner's pain might facilitate their efforts to informally settle the case (in particular because their primary point of dispute centered on the amount of pain and suffering to allow). See Scheduling Order at 1, ECF No. 27. Respondent's counsel also noted that, during Petitioner's July 17, 2018 surgery, the orthopedic surgeon observed a type 2b SLAP⁵ lesion, a condition Respondent maintains is not consistent with a SIRVA Injury. See Scheduling Order at 2. When asked if the parties wished to submit any additional evidence or argument regarding onset, Petitioner's counsel requested ten days to confer with Petitioner. Respondent's counsel indicated that Respondent would only wish to respond to any additional filings from Petitioner. *Id.* at 1. On July 16, 2021,

neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

⁴ Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

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⁵ SLAP stands for Superior Labrum Anterior Posterior. MEDICAL ABBREVIATIONS at 552 (16th ed. 2020).

Petitioner filed a status report indicating he did not wish to supplement the record prior to my factual finding regarding the onset of his pain. ECF No. 28.

I have determined that a factual finding regarding the onset of Petitioner's SIRVA is required in this case, and will assist in its ultimate disposition. The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and QAI for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make my finding regarding onset after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I base the finding on the following evidence:

• When Petitioner first sought medical care for his right shoulder pain, 27 days post-vaccination on November 29, 2017, he described (on the New-Injury Patient Information Form he completed) "[s]houlder pain all the way down to [his] elbow" which he attributed to the flu shot he had received earlier that same month. Exhibit 8⁶ at 4. However, he did not provide any information regarding the timing of his pain. In the portion of the medical record which

⁶ Exhibit 8 at 1-4 is a better copy of the record from Petitioner's November 29, 2017 visit to Baptist Occupational Health, which was previously filed as Exhibit 2 at 16-19. Any citation to this medical record will be to the easier to read version filed as Exhibit 8.

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appears to have been completed by the provider,⁷ there is an entry which reads as follows: "Duration: symptoms since work-injury/date: ~ 11.10.17." *Id.* at 2. The location of Petitioner's pain is listed as the right shoulder, arm, forearm, and elbow, and the pain is attributed to the flu vaccine Petitioner received. Bruising, swelling, and tenderness was noted along the right upper deltoid and shoulder. *Id.*

- At his initial PT session on December 1, 2017, Petitioner reported "that he received a flu shot at work about one month ago at work [and his] symptoms started about two days later." Exhibit 2 at 24. These symptoms were described as "[t]enderness in the biceps tendon (proximal), bicipital groove, infraspinatus tendon, subacromial bursa and supraspinatus tendon." *Id.* at 25.
- When seen by an orthopedist, on December 6, 2017, Petitioner identified the onset of his right shoulder pain as occurring "about six weeks ago after a flu shot." Exhibit 3 at 22. Although he did not show any tenderness, he demonstrated evidence of impingement. *Id.* at 24-25.
- When he returned to the orthopedist on January 5, 2018, Petitioner stated "[h]e was injured 11 weeks ago by a flu shot." Exhibit 3 at 26. He described his pain as aching and shooting, at a level of ten out of ten. *Id.* This description of the onset of Petitioner's pain was repeated in the record containing the results of an MRI, performed on January 8, 2018. Exhibit 4 at 12.
- At Petitioner's third visit to the orthopedist, on January 19, 2018, he reported that "[h]e had a flu shot [the] second week of November [and] . . . has had pain and tendinitis since then." Exhibit 3 at 31. The orthopedist noted that the MRI showed no acute pathology but "some incidental findings of a subchondral cyst and chronic wear." *Id.* at 33. A cortisone injection was administered at that visit. *Id.* at 34.
- The medical record from Petitioner's next orthopedic visit, on February 9, 2018, lists the correct vaccination date - November 2, 2017. Exhibit 3 at 35. However, there is no additional information in this record regarding the onset of Petitioner's injury.

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⁷ Compare Exhibit 8 at 4 with id. at 2 (revealing differences in the handwriting found on the New-Injury Patient Information Form and other portions of this record).

- Petitioner did not return to the orthopedist until May 30, 2018. Exhibit 3 at 39-43. In the record from this visit, it was noted that Petitioner had a flu shot last November and "afterwards he developed an inflammatory response." Id. at 39.
- When seen next by the orthopedist, on July 1, 2018, Petitioner described his right shoulder pain as "start[ing] the morning after a flu shot injection in November." Exhibit 3 at 43. Petitioner's injury was described as "an inflammatory response," and he was characterized as "miserable with pain." Id. Arthroscopic surgery was performed on Petitioner's right shoulder on July 17, 2018. Exhibit 5.

In every post-vaccination record containing a medical history, from the time he first sought treatment on November 29, 2017, Petitioner consistently attributed his injury to the flu vaccine he received on November 2, 2017. Although he often provided a timeframe for his injury which would not coincide with the vaccination he received, he applied the same incorrect timeframe to the vaccination as well. See Exhibits 3 at 22, 26, 31 (regarding visits on December 6, 2017 and January 5 and 19, 2018). These errors are evidence that Petitioner was not an exact historian regarding the timing of both his vaccination and injury. They do not undercut Petitioner's claim regarding onset as Respondent argued. See Rule 4(c) Report at 6. Rather, Petitioner's consistent linking of injury to vaccination supports his claims of onset - albeit only generally.

In three instances, Petitioner provided more specific information placing onset closer-in-time to vaccination. For example, at his initial PT visit on December 1, 2017, Petitioner indicated his pain began two days after vaccination. Exhibit 2 at 24. Depending on the timing of his vaccination and pain, this entry could describe onset slightly less or more than 48 hours post-vaccination. Then, on January 19, 2018, Petitioner described his pain as occurring "since" vaccination. Exhibit 3 at 31. This entry implies a more immediate onset. Finally, on July 1, 2018, Petitioner reported that his pain began the morning after vaccination, which would be less than 48 hours post-vaccination. *Id.* at 43.

When arguing that Petitioner has not satisfied the onset requirement for a Table SIRVA, Respondent emphasizes an entry in the medical record from Petitioner's initial visit, on November 27, 2017, for his right shoulder pain. In response to the prompt "Duration: symptoms since work-injury/date:," the provider listed the date of November 10, 2017. Exhibit 8 at 2. Respondent maintained this entry shows the onset of Petitioner's pain occurred eight days post-vaccination. Rule 4(c) Report at 6. However, there are several problems with that characterization.

Although purporting to provide the duration of Petitioner's symptoms, this entry consists of only a single date. It contains no information regarding the time between Petitioner's symptoms and the vaccination alleged as causal - the date of vaccination is not provided in the record from this visit. Given Petitioner's propensity to misstate the date of vaccination as well as the date of his injury, it cannot be assumed that he was indicating an eight-day period for the onset of his pain when providing the November 10th date. Additionally, the wording of the prompt for this entry is unclear – it could be interpreted as requesting the date of the work-injury rather than first symptom. Without further explanation, the meaning of the November 10, 2017 date is uncertain. For these reasons, the probative value of this entry, containing only a date, is not what Respondent urges, especially given other subsequent records more consistent with a Table onset.

Although a close call, the record as a whole supports Petitioner's description of pain within 48 hours of vaccination.⁸ Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain is consistent with the Table SIRVA requirement.

V. Other Issues Relevant to Entitlement and Compensation

Although I have determined that the onset of Petitioner's right shoulder pain occurred within the time period required for a Table SIRVA, Petitioner must also satisfy the additional criteria for a Table SIRVA, or provide preponderant evidence of causation to show he is entitled to compensation in this case. Additionally, even if the parties agree, or I determine, that Petitioner is entitled to compensation, there are matters which must be considered when determining the amount of compensation to be awarded. I address some of these matters below in the hope of facilitating and assisting settlement of the matter.

The medical records reveal that Petitioner suffered tendonitis, most likely in only his right elbow, prior to vaccination. When he first sought medical care for his right shoulder pain on November 29, 2017, Petitioner indicated he had suffered from tendonitis one and one-half years earlier. Exhibit 8 at 3. The location of the tendonitis is not provided, but a prior diagnosis of lateral and medial epicondylitis of the right elbow⁹ is listed in the medical record from Petitioner's December 6, 2017 visit to his orthopedist. Exhibit 3 at

⁸ See Althen, 418 F.3d at 1280 (the Federal Circuit's instruction that close calls should be resolved in favor of the petitioner).

⁹ Lateral epicondylitis is "an overuse injury of the lateral humeral epicondyle at the elbow, due to inflammation or irritation of the area where the extensor tendon attaches to it," popularly known as tennis elbow. Dorland's Illustrated Medical Dictionary at 630 (32th ed. 2012). Medial epicondylitis is "an overuse injury with pain around the medial epicondyle of the humerus where the flexor muscles of the arm and hand attach," popularly known as golfer's elbow. *Id*.

22. While there are no entries indicating Petitioner suffered from prior right *shoulder* pain, the earlier pain in his right elbow may, at a minimum, complicate the issue of compensation. Petitioner should be sensitive to this matter in formulating his demand.

Additionally, there are entries in the medical records indicating the right shoulder pain Petitioner experienced post-vaccination occasionally radiated into his elbow, left forearm, and fingers. By December 13, 2017, Petitioner reported more soreness, deeper pain, and occasional numbness in the top of his fourth digit. Exhibit 2 at 50. And there is clear evidence Petitioner suffered a SLAP tear. Exhibit 5 at 1. These issues will also need to be considered when determining if Petitioner is entitled to compensation, and when determining the amount of compensation to be awarded. It is foreseeable that pain and medical care associated with such non-SIRVA sequelae would not be awarded.

I would also note, however, that Petitioner suffered significant levels of pain prior to undergoing SIRVA-related surgery on July 17, 2018. *E.g.,* Exhibit 3 at 31 (containing reports of pain at a level of ten out of ten); see Exhibit 5 (medical records from surgery). Generally, surgery is required in more severe SIRVA cases – and I have in prior matters noted that the need for surgery justifies a higher-than-average pain and suffering award. Respondent is advised to keep this in mind in negotiating settlement.¹⁰

VI. Scheduling Order

In light of my finding regarding onset, the parties should resume their settlement discussions to determine if they can informally resolve this case. The parties shall file a joint status report regarding their settlement discussions by no later than <u>Friday</u>, <u>September 03, 2021</u>. In the status report, the parties should indicate whether they believe an informal settlement can be reached and if so, when they believe the case can be informally resolved.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master

¹⁰ E.g., Smith v. Sec'y of Health & Human Servs., No. 19-0745V, 2021 WL 2652688 (Fed. Cl. Spec. Mstr. May 28, 2021) (noting any surgical intervention is often evidence of the suffering a petitioner was experiencing).